

Errol B. Taylor (ET 6742)
John M. Griem, Jr. (JG 2609)
MILBANK, TWEED, HADLEY &
McCLOY LLP
1 Chase Manhattan Plaza
New York, New York 10005-1413
(212) 530-5000

Attorneys for Plaintiffs
and Counterclaim-Defendants
AstraZeneca AB, Aktiebolaget Hässle,
AstraZeneca LP, KBI Inc. and KBI-E Inc.

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

	X
	:
ASTRAZENECA AB,	:
AKTIEBOLAGET HÄSSLE and	:
ASTRAZENECA LP,	:
KBI INC. and KBI-E INC.,	07-CV-6790 (CM)(GWG)
	:
Plaintiffs and	:
Counterclaim-Defendants,	ELECTRONICALLY FILED
	:
v.	:
	:
DR. REDDY'S LABORATORIES, LTD. and	:
DR. REDDY'S LABORATORIES, INC.	:
	:
Defendants and	:
Counterclaim-Plaintiffs.	:

X

**ASTRAZENECA'S MEMORANDUM OF LAW IN SUPPORT OF
ASTRAZENECA'S MOTION TO STRIKE NEW DECLARATIONS AND ARGUMENTS
SUBMITTED WITH DRL'S SUMMARY JUDGMENT MOTION REPLY**

TABLE OF CONTENTS

	<u>Page(s)</u>
I. INTRODUCTION.....	1
II. DRL'S NEW REPLY EVIDENCE SHOULD BE STRIKEN	2
A. The Declaration Of Dr. Kumara Sekar And Related Arguments Should Be Striken	3
B. The Third Declaration Of Harry G. Brittain And Related Arguments Should Be Striken.....	4
C. The Third Declaration of Louis H. Weinstein And Related Arguments Should Be Striken.....	5
III. CONCLUSION	6

TABLE OF AUTHORITIES

	<u>Page(s)</u>
CASES	
<i>Bristol-Myers Squibb Co. v. Royce Labs., Inc.</i> , 69 F.2d 1130 (Fed. Cir. 1995).....	4
<i>Giannullo v. City of New York</i> , 322 F.3d 139 (2d Cir. 2003).....	3
<i>Metropolitan Life Insurance Co. v. Bancorp Services LLC</i> , 527 F.3d 1330 (Fed. Cir. 2008).....	3, 5
<i>Playboy Enters. v. Dumas</i> , 960 F.Supp. 710 (S.D.N.Y. 1997)	2
<i>Sigmon v. Parker Chapin Flattau & Klimpl</i> , 901 F.Supp. 667 (S.D.N.Y. 1995)	2
STATUTES	
35 U.S.C. §271(g)	2, 5
RULES	
Fed. R. Civ. P. 26.....	3

Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc., and KBI-E Inc. (collectively, "AstraZeneca") hereby move to strike the new evidence and arguments Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") relies on for the first time in reply to AstraZeneca's opposition to DRL's motion for summary judgment. Alternatively, if the Court is inclined to consider any information set forth for the first time in DRL's new Declarations, AstraZeneca requests permission to file a sur-reply to address the new facts and arguments raised in the Declarations.

I. INTRODUCTION

DRL presents three new Declarations containing new evidence and makes new arguments for the first time in its reply in support of its motion for summary judgment. DRL submits the Declaration of Kumara Sekar, Ph.D., the Third Declaration of Harry G. Brittain, Ph.D., FRSC, and the Third Declaration of Louis H. Weinstein. These new Declarations and DRL's arguments relying on the new Declarations should have been included with DRL's moving papers and should be stricken.

DRL had ample opportunity to submit all of its evidence with its summary judgment motion, and chose not to include the facts in the new Declarations. On July 9, 2008, DRL filed a motion for summary judgment that was supported by a Local Civil Rule 56.1 Statement, the Second Declaration of Louis H. Weinstein and the Second Declaration of Harry G. Brittain, Ph.D., FRSC.

AstraZeneca's July 30, 2008 opposition papers detailed the evidentiary inadequacies of DRL's evidence, the fact that Dr. Brittain's Second Declaration is based only on uncorroborated hearsay statements, such as DRL's interrogatory responses, and includes an oversimplified and misleading summary of DRL's manufacturing process. (AstraZeneca Memo Sec. III.B-C; Luk Declaration ¶¶ 39-45). In addition, AstraZeneca noted that DRL produced no

admissible evidence that the samples it had provided are representative of its ANDA Products, and no information regarding how the samples were collected and handled. (AstraZeneca Memo Sec. II.C). Nor did DRL attempt to authenticate or establish the admissibility of the DMF and ANDA documents it had produced; in fact, DRL made no mention whatsoever of those documents, let alone rely on them as direct evidence of DRL's ANDA product and processes.

Now, in DRL's August 13, 2008 reply, DRL relies on three new declarations: the Declaration of Kumara Sekar, the Third Declaration of Dr. Brittain and the Third Declaration of Mr. Weinstein. DRL makes new arguments based on those Declarations which attempt to overcome the glaring evidentiary problems AstraZeneca predictably identified in DRL's motion. The Court should strike the new Declarations and not consider any of the arguments DRL makes based on them.

DRL's new arguments and Declarations highlight other glaring omissions from DRL's reply, and distort the record. DRL does not address all the bases for infringement asserted by AstraZeneca, including infringement under 35 U.S.C. §271(g). DRL continues to refuse to authenticate properly the few samples it produced to AstraZeneca, leaving those samples worthless as evidence of the properties of DRL's ANDA Products. And, DRL's reply incorrectly suggests that AstraZeneca has not identified the claims that would be infringed by DRL's Products. In fact, AstraZeneca specifically outlined these claims in its opposition to summary judgment. (*See infra* p. 5).

II. DRL'S NEW REPLY EVIDENCE SHOULD BE STRIKEN

A court should not consider evidence and arguments made for the first time in a reply brief. *See Playboy Enters. v. Dumas*, 960 F.Supp. 710, 720 n.7 (S.D.N.Y. 1997); *Sigmon v. Parker Chapin Flattau & Klimpl*, 901 F.Supp. 667, 677 n.5 (S.D.N.Y. 1995).

A. The Declaration Of Dr. Kumara Sekar And Related Arguments Should Be Striken

DRL's reliance on the declaration of Dr. Kumara Sekar to authenticate its ANDA and DMF documents is an untimely attempt to obviate a glaring lack of evidence that doomed DRL's motion for summary judgment. On summary judgment, the movant must point to the evidence in the record that establishes that it is entitled to summary judgment. *Giannullo v. City of New York*, 322 F.3d 139, 140-41 (2d Cir. 2003). DRL cannot now attempt to cure the insufficiency of its evidence by introducing the ANDA and DMF via the declaration of Dr. Sekar. DRL has not provided any excuse for its untimely attempt to put selected ANDA and DMF documents in the record, so the Sekar Declaration and all references to it in DRL's reply papers should be stricken. (DRL Reply Sec. II.A, III).

Dr. Sekar's declaration should also be stricken because AstraZeneca has not had any opportunity to depose Dr. Sekar. Indeed, AstraZeneca did not even know he existed because DRL has not been required to comply with Fed. R. Civ. P. 26 Initial Disclosure requirements. As the Federal Circuit emphasized in *Metropolitan Life Insurance Co. v. Bancorp Services LLC*, 527 F.3d 1330, 1338 (Fed. Cir. 2008) ("MetLife"), it is improper on a summary judgment motion for a court to rely on declarations from witnesses the opposing party has not been permitted to depose after an opportunity to conduct general discovery.

Because AstraZeneca has not had a chance to depose Dr. Sekar, it has had no opportunity to test the basis of his statements, or complete the record with other relevant documents and testimony that may exist. DRL has produced only certain sections of its ANDA and DMF, and AstraZeneca has not been permitted to learn from Dr. Sekar if those sections comprise all the relevant portions of the ANDA and DMF.

Crucially, DRL does not attempt to cure the most important evidentiary failures in its new reply Declarations. DRL has produced no evidence that the samples it provided to AstraZeneca are representative of the product it intends to market, or that the produced portions of its ANDA and DMF accurately describe the product it intends to market. Contrary to DRL's arguments, it is the intended product that should be the focus of discovery and the Court's infringement determination. *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.2d 1130, 1135 (Fed. Cir. 1995).

B. The Third Declaration Of Harry G. Brittain And Related Arguments Should Be Striken

The Third Declaration of Harry G. Brittain, like Dr. Sekar's declaration, is a belated attempt to fix an evidentiary problem that defeats DRL's motion for summary judgment. There is no reason why Dr. Brittain could not have reviewed the DMF and ANDA documents before submitting his Second Declaration. For this reason alone, Dr. Brittain's Third Declaration should be striken.

Dr. Brittain's new Declaration should also be striken as conclusory hearsay. As explained is AstraZeneca's opposition to DRL's motion, Dr. Brittain's Second Declaration is based on inadmissible hearsay and cannot be relied on by the Court. (AstraZeneca Memo Sec. III.B)). In his Third Declaration, Dr. Brittain attempts to remedy the fundamental flaws in his Second Declaration by broadly stating that he has finally reviewed DRL's ANDA and DMF and agrees with his previous positions. AstraZeneca's opposition and Dr. Luk's Declaration submitted therewith explain that the DMF and ANDA documents do not provide enough information to credibly or scientifically support Dr. Brittain's argument that DRL's process does not include the addition of water. (AstraZeneca Memo Sec. V.B, Luk Declaration at ¶¶ 29-37). Dr. Brittain's Third Declaration does not respond to AstraZeneca's detailed criticisms of DRL's

ANDA and DMF. Since AstraZeneca has not had any chance to depose Dr. Brittain, his testimony cannot be credited, especially in the face of factual disputes like these. *MetLife*, 527 F.3d at 1337-38. Dr. Brittain's Third Declaration is no more admissible than his Second.

The unreliable nature of Dr. Brittain's Third Declaration is demonstrated by the fact that he does not attempt to refute AstraZeneca's evidence that DRL's ANDA Products may infringe AstraZeneca's process claims under 35 U.S.C. §271(g). (AstraZeneca Memo Sec. V.C). Dr. Brittain's new declaration does not explain how AstraZeneca or the Court can possibly know that DRL's product does not infringe during manufacture since AstraZeneca has been not been provided in-process samples of DRL's ANDA Products.

The Third Brittain Declaration is also obviously wrong on key issues. Dr. Brittain says that Dr. Luk did not conclude that DRL infringed any claims, when Dr. Luk did just that. Dr. Luk concluded that DRL's process is covered by '424 patent claims 11 and 20. (Luk Declaration ¶¶ 55-56). He also concluded that disputed issues of fact requiring further discovery existed for the other independent claims. (Luk Declaration ¶¶ 6, 7, 11-13, 15, 20, 21, 30, 32).

Dr. Brittain had a full opportunity to review DRL's ANDA and DMF prior to DRL's motion for summary judgment. He chose not review those documents and instead based his entire opinion on DRL's flawed interrogatory responses. Dr. Brittain should not be permitted to completely alter the basis of his opinions in a cursory declaration submitted on reply. Dr. Brittain's Third Declaration should be stricken.

C. The Third Declaration of Louis H. Weinstein And Related Arguments Should Be Stricken

Mr. Weinstein's Third Declaration attempts to introduce new evidence regarding the completeness of DRL's document production that should not be considered by the Court. Mr. Weinstein purports to characterize conversations between himself and AstraZeneca's

counsel in an attempt to establish that DRL produced all relevant portions of the DMF and ANDA, and all portions requested by AstraZeneca. These summaries were not included in DRL's Rule 56.1 Statement submitted with its motion for summary judgment, and so should be stricken. Moreover, AstraZeneca has not had an opportunity to respond to the factual inaccuracies in Mr. Weinstein's new declaration and will be prejudiced if the Court accepts Mr. Weinstein's accounts of the conversations as true or complete. Even the documents attached to Mr. Weinstein's new Declaration show that AstraZeneca requested a complete copy of DRL's ANDA and DMF. (Griem 56(f) Affidavit, Ex. 20, Email Griem to Weinstein, May 16, 2008). AstraZeneca did so before this action began (Griem 56(f) Affidavit, Ex. 4, Letter Taylor to Banks, July 3, 2007), and AstraZeneca still needs complete copies to determine the ANDA Product composition and processes currently proposed by DRL. Consequently, AstraZeneca respectfully requests that the Court strike Mr. Weinstein's Third Declaration and related arguments. (DRL Reply Sec. II.C).

III. CONCLUSION

For the foregoing reasons, AstraZeneca respectfully requests that the Court strike DRL's Declaration of Kumara Sekar, Third Declaration of Louis H. Weinstein and Third Declaration of Harry G. Brittain and all arguments relying on this new evidence, submitted with DRL's reply to AstraZeneca's opposition to DRL's summary judgment motion. Alternatively, if the Court is inclined to consider DRL's new Declarations, AstraZeneca respectfully requests leave to file a sur-reply so that it may substantively address DRL's belated facts and arguments.

Date: August 21, 2008

By: s/ John M. Griem, Jr.
 Errol B. Taylor (ET 6742)
 John M. Griem, Jr. (JG 2609)
 MILBANK, TWEED, HADLEY &
 McCLOY LLP

1 Chase Manhattan Plaza
New York, New York 10005-1413
(212) 530-5000
Attorneys for Plaintiffs
and Counterclaim-Defendants
ASTRAZENECA AB,
AKTIEBOLAGET HÄSSLE,
ASTRAZENECA LP, KBI INC.
AND KBI-E INC.

CERTIFICATE OF SERVICE

I certify that on this 21st day of August 2008, I caused a true and correct copy of the foregoing **ASTRAZENECA'S MEMORANDUM OF LAW IN SUPPORT OF ASTRAZENECA'S MOTION TO STRIKE NEW DECLARATIONS AND ARGUMENTS SUBMITTED WITH DRL'S SUMMARY JUDGMENT MOTION REPLY** be served upon counsel for DRL in the following manner:

BY FEDERAL EXPRESS

Louis H. Weinstein, Esq.
Michael Imbacuan, Esq.
BUDD LARNER
150 John F. Kennedy Parkway
Short Hills, NJ 07078-2703
Facsimile: (973) 379-7734

Ani Brat